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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/466,778	12/20/99	HASTINGS G	PF487

022195
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
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HM22/0425

EXAMINER	
MITRA,R	

ART UNIT	PAPER NUMBER
1653	6

DATE MAILED: 04/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/466,778	HASTINGS ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any *earned patent term adjustment. See 37 CFR 1.704(b).*

Status

1)☒ Responsive to communication(s) filed on *20 February 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

Applicants' election with traverse of Group XXIX (claims 11 and 12) in paper #9 (filed on February 20, 2001) is acknowledged. The claims 2-12 and 14-16 have been canceled. Claims 1,13, 17-22 have been withdrawn as being non-elected claims. The new claims (23-80) have been added (paper #9). Therefore, claims 23-80 are currently pending and are under examination.

Response to Traversal of Restriction Requirement

Applicants' election with traverse of group XXIX (claims 11-12) in Paper NO. 9 is acknowledged. The traversal is on the ground(s) that separate and diverse searches of groups I-XXXVI directed to nucleic acids related to WF-HABP, OE-HABP, BM-HABP set forth in SEQ ID NO: 1, 4, and 7 and 10 respectively; polypeptides related to WF-HABP, OE-HABP, BM-HABP set forth in SEQ ID NO: 2, 5, and 8 and 11 respectively; antibody; method for gene therapy using polynucleotides and polypeptides; method for diagnosing pathological conditions related to polynucleotides and polypeptides; method for identifying a binding partner to

polypeptide; method for identifying compounds capable of affecting the response induced by polypeptide, would not be required. Applicants submit that it is incumbent upon the Examiner to conduct a search of all of the claimed subject matter. This is not found persuasive because a search of the polynucleotide claims would not and does not necessarily encompass claims directed to methods for selecting a compound which modulates the response induced by polypeptides related to WF-HABP, for example; an antibody capable of binding to polypeptides related to WF-HABP, for example. The prior art pertaining to these patentably distinct subject areas is vastly different. For example, many publications provide no sequence data at all making it difficult if not impossible to establish a link between a given polynucleotide sequence and a corresponding polypeptide or related methods, therapies and antibodies. It would constitute an undue burden on Examiner to search claims directed to the polynucleotides of groups I, X, XIX, XXVIII, and the distinct inventions of groups II-IX, XI-XVIII, XX-XXVII and XXIX-XXXVI for precisely this reason. For example, the prior art is replete with examples of proteins, which have been isolated and purified, but only much later sequenced and the corresponding cDNA cloned. Therefore, on its face, a search of the polynucleotide claims would not encompass claims to the methods using the polypeptides for identification of compounds and antibodies selective for the polypeptide, *etc.* Consequently, a search of claims directed to these patentably distinct groups together would constitute an undue burden.

Applicants have requested (page 9, paper #9) that upon indication of allowable subject matter, the Examiner rejoin the claims of Group XXIX with Group XXXIV. This is not persuasive because the inventions XXIX and XXXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the polypeptide of group XXXIX can be used in other materially distinct processes from those set forth in group XXXIV, such as the immunization of a mammal for the production and isolation of antibodies.

The restriction requirement is still deemed proper and is therefore made **FINAL**.

Objections to the Specification

On page 3, line 30 under 'Brief Description of the Figure' the specification reads as SEQ ID NP: 11 instead of SEQ ID NO: 11.

Specification indicates on page 20, line 22 that the Figures 4A-B depict SEQ ID NO: 8 (BM-HABP cDNA) and on line 25-27 it indicates OE-HABP protein shown in Fig 4A-B (SEQ ID NO: 10) is predicted to be about 43% identical to the TSG protein depicted in SEQ ID NO: 11(Fig. 8A-B) while on page 16, lines 5-9 it indicates that the BM-HABP protein (Fig, 4A-B(SEQ ID NO: 11) shares homology with TSG-6 protein (Fig 8(SEQ ID NO: 11))

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claims 23-80 are rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed polynucleotides are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed polynucleotides or the encoded proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed polynucleotides or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed. The reasons are as follows:

The specification, on pages 16 and 20 describes protein set forth in SEQ ID NO: 11 to which the instant invention relates. Specification page 16 indicates that based on alignment with database submission the claimed polypeptide shares sequence homology with the Mus musculus TSG-6 protein (Fig 8 (SEQ ID NO: 11)). Further based on the structural similarity by having hyaluronan binding domain the claimed protein shares some specified activity with this submission. The alignment of SEQ ID NO: 11 (Fig 8) has been provided but no percent similarity is disclosed.

A sequence identity search for SEQ ID NO: 11 using GenBank database indicates the alignments and percent similarity to sequence cited by the applicants and indicated having similar activity (specification page.16), identified as Accession NO:

W84087 (Lee et al., Dec 8, 1998) teach a TSG-6 protein, having 43% sequence identity to SEQ ID NO: 11 (see alignment result, A_Geneseq_36 database and US Patent 5,846, 763, Dec 8, 1998, Example V). Lee et al. also teach a TSG 6 protein, having 37% sequence identity to adhesion receptor CD44 (J. of Cell Biology, vol. 116, NO. 2, pp. 545-557, Jan 1992; see Figs. 4, 5 and col.1, page 551)

Further, a sequence identity search for SEQ ID NO: 11 using GenBank database indicates the alignments and percent similarity to sequences, identified as Accession NOs:

Q9NRY3 (Tao et al., Oct 1, 2000) teach a CD44-like precursor FELL, having 93.8% sequence identity to SEQ ID NO: 11 (see alignment result, SPTREMBL_15 database).

Q9UF98 (Blum et al., May I, 2000) teach a hypothetical 115.7 KDA protein fragment, having 80.5% sequence identity to SEQ ID NO: 11 (see alignment result SPTREMBL_15 database).

Thus, the foregoing indicates that the sequence of SEQ ID NO: 11 of the instant application has a lower percentage similarity (43%) to the sequence of W84087 (TSG-6 protein) while it has a much higher percentage similarity (93.8% and 80.5%) to Q9NRY3 (CD44 like receptor) and Q9UF98 (a hypothetical protein) respectively. Therefore, only on the basis of some similarity to sequences identified as TSG-6 protein, the protein of SEQ ID NO: 11 can not be identified as a member of 'TSG-6 (HABP)' family. If the protein has similar activity, it would have indicated close sequence similarity with W84087.

In *Ex parte Dash* (Bd Pat App 7 Int 27 USPQ2d 1481) the Board sustained the rejections under lack of enablement based on reasons which also apply to the prior art. Therefore, it is not inconsistent to reject claims for lack of enablement as well as being taught in the prior art.

Based on the specification (pages 3, 5, 8, 10, 11), any biological activity of the polypeptide itself has not been provided. However, uses have been provided on pages 9-11 and 210-332 of the specification, but are discussed in the context of being used for further research, but to do what? The function/biological activity of the protein is not per se set forth in the instant specification. One skilled in the art should not have to engage in discovering genomics to learn how to use the invention. This situation requires carrying out future additional research to

identify or reasonably confirm a "real world" context of use and therefore do not define specific and substantial utility.

Other activities that the protein may exhibit are listed throughout pages 210-332 of the specification. However, these activities are not demonstrated. In summary, the polypeptides claimed do not have a credible, specific or well-established utility and therefore lacks utility under 35 U.S.C. 101.

Claims 31, 32, 36, 37, 41-44, 48-51, 55-68 and 72-77 are drawn to a protein comprising a fragment of SEQ ID 11. The specification does not describe the functional properties of these protein fragments, and the structural information is limited. While the specification enumerates several known assays for biological activity (p. 215-223), it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed fragments.

Claim 27 is drawn to a protein comprising the full-length polypeptide encoded by the cDNA contained in ATCC Deposit NO: 203502. It is not clear from the description of the clone (specification pages 15-16) about the protein structure, aside from its full-length amino acid sequence, and/or its function.

Claims 24, 28, 33, 38, 45, 52, 69 and 78 are directed to a protein comprising a heterologous polypeptide sequence. It is not clear from the description of the heterologous proteins (specification page 40) about the protein structure and/or its function.

Claims 25, 29, 34, 39, 46, 53, 70 and 79 are drawn to a composition comprising the protein of SEQ ID NO:11 and its fragments. Applicants assert on page 337-338 that the composition would be useful in the treatment of conditions associated with disease. Examples of many therapeutic methods have been described in pages 272-332 but the specification does not indicate explicitly the correlation of the role of this composition to a specific disease treatment.

Claims 26, 30, 35, 40, 47, 54, 71 and 80 are drawn to a protein produced by the method comprising expressing the protein by a cell and recovering the protein. Specification on page 56-69 describes the vectors and host cells but does not indicate the function of the expressed protein.

As discussed above, based on the specification it is unclear what activity the claimed proteins or protein fragments possess and therefore unclear how a person having skill in the art might use the claimed polypeptides. It would require undue experimentation for a person having skill in the art to be able to use the claimed polypeptides. It is *a priori* unpredictable based on the instant disclosure what activity the claimed polypeptides possess because no correlation has been made between the claimed polypeptides and a specific activity.

In the instant case, the failure of applicants to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the protein set forth in SEQ ID NO: 11 other than the fact that the protein may be hyaluronan binding protein (p. 3). The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 11 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified biological activity or that do not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-80 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 31, 32, 36, 37, 41-44, 48-51, 55-68 and 72-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31, 32, 36, 37, 41-44, 48-51, 55-68 and 72-77 are indefinite since it is unclear by absence in the claim recitation whether or not the polypeptide fragments are active, or what that activity may be.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.
April 19, 2001

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